

REMARKS

Claims 1-5 were pending at the time of the mailing of the outstanding Office Action. By this amendment, claim 1 has been amended to include the elements of claim 3, which has been cancelled without prejudice or disclaimer as to the subject matter contained therein. No claims have been added.

In the Office Action of 10 December 2008, the examiner rejected claims 1-2 under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent No. 7,169,178 to Santos et al. (hereinafter "Santos"). Under 35 U.S.C. § 103(a), the Examiner rejected claim 3 as being obvious over Santos and claims 4-5 as being obvious over Santos in view of U.S. Pat. No. 5,972,027 to Johnson (hereinafter "Johnson").

Claim 1 has been amended to include the elements of claim 3, namely, that a degradation behavior of the carrier serves to differentiate the local elution characteristics. Therefore the rejection under 35 U.S.C. § 102(e) is now believed to be moot.

In the Office Action, Santos is cited as providing a stent comprising a basic tubular body with a coating system comprising a polymer carrier and a pharmaceutically active substance, wherein a concentration of the pharmaceutically active substance varies in the longitudinal direction of the stent. Santos is also indicated to teach a biodegradable coating material. It was alleged that the use of the degradation characteristics of the polymer to differentiate local elution characteristics would have been inherent in the disclosure of Santos,

or that such a use would have been obvious to one of ordinary skill in the art at the time of the invention. However, it was stated, “Santos is silent as to whether the degradation behavior of the carrier serves to differentiate local elution characteristics.” (Page 3, Paragraph 6.)

A claimed invention is unpatentable under 35 U.S.C. §103 if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103 (1994); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, No. 04-1350, *slip op.* at 2 (2007). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *KSR Int'l* at 2.

To reach a proper determination under §103, the Examiner must step backward in time and into the shoes of the hypothetical person of ordinary skill in the art when the invention was unknown and just before it was made. MPEP §2142. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP §2142.

The Applicants maintain that the Examiner has not properly considered the teachings of Santos as a whole and has therefore found the desirability of its modification with the aid of hindsight provided by the claimed invention.

None of the rationales for a finding of obviousness, as enunciated by the Supreme Court in *KSR*, were provided in the Office Action. It was not alleged that the claims would have resulted from combining known elements to yield predictable results, or that they would have resulted from simple substitution of one known element for another to obtain predictable results. It also was not alleged that the invention was obviousness because it involved use of a known technique to improve a similar device in the same way. Nor was it alleged that the modification in question involved applying a known technique to a device, method or product ready for improvement to yield predictable results. No allegation was made that the alleged obviousness stemmed from a choice from a finite number of identified, predictable solutions with a reasonable expectation of success. Finally, no allegation was made that known work in one field or a different one would prompt variations of it for use in the same field or a different one, based on design incentives or other market forces, to provide predictable results.

Furthermore, there was no allegation of any teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify Santos as indicated in the Office Action. Only a bare allegation was made that the modification was obvious because “the rate of polymeric degradation would affect the amount of drug released from that polymer.” However, in the absence of evidence of the predictability of such an effect to one of ordinary skill in the art, such a statement only reflects

the impermissible use of hindsight to reject the claims. Therefore, the Applicants maintain that a prima facie case of obviousness of claim 1 (formerly claim3) has not been established.

Claims 4-5 stand rejected as being obvious over Santos in view of Johnson. It was alleged that Johnson teaches the use of multiple drugs with different concentrations based on the porosity of the stent and that it would have been obvious to one of ordinary skill in the art to provide a coated stent with variable drug concentrations in the coating as provided by Santos with the release profile as taught by Johnson. However, such a proposed combination would change a principle of operation of Johnson. Such a modification is impermissible under MPEP 2143.01. The embodiment of Johnson cited as providing different concentrations of a drug in different areas of the stent does so based on the porosity of the stent material itself. In contrast, the claimed invention relies on the degradation behavior of a polymer to release the drug or drugs, not on the presence or size of pores in the structure. Johnson provides no indication that degradation plays any role in the release of a therapeutic agent. The proposed combination of Santos and Johnson would alter a principle of operation of the invention of Johnson rendering such a combination non-obvious. Withdrawal of the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) is respectfully requested.

In light of the arguments provided above, the Applicants maintain that the pending claims distinguish over the cited prior art. The issuance of a Notice of Allowance is respectfully requested.

Because the amendment presented herein place the claims under consideration in condition for allowance, entry of this Amendment after Final Rejection is appropriate. Only claim 1 has been amended and then only to incorporate the elements of claim 3. The amendment will not necessitate an additional search. In the event that the Examiner disagrees with the Applicants regarding the allowability of the pending claims, entry of the Amendment should still be made on the grounds that amendment of claim 1 and cancellation of 3 simplifies matters under consideration for appeal.

The outstanding Office action was transmitted on 10 December 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. A petition for a one month extension of time is hereby made with this response. Additionally, the Applicants hereby make a conditional petition for any additional extension of time for response in the event that such a petition is required. The Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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